Clinical Commissioning Policy: Proton Beam Radiotherapy (High Energy) for Teenage and Young Adult Cancer Treatment – NHS Overseas Programme

Reference: NHS England B01/P/c

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Additional Circulation List	Regional Medical Directors; Regional Directors of Specialised Commissioning; Regional Clinical Directors of Specialised Commissioning; Regional Directors of Nursing
Description	NHS England will routinely commission this specialised treatment in accordance with the criteria described in this policy.
Cross Reference	
Superseded Docs (if applicable)	
Action Required	
Timing / Deadlines (if applicable)	
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Document Status

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1 Executive summary

Policy statement

NHS England will commission High Energy Proton Radiotherapy for a specific subset of Teenage and Young Adult (TYA) cancers. Initially this activity will be provided through the NHS Proton Overseas Programme, in accordance with the criteria outlined in this document. However, on establishment of a proton beam service for the United Kingdom (UK) (currently planned to begin in 2018) the indications outlined within this policy will delivered by the UK service. There is currently insufficient evidence to support routine commissioning abroad in other indications for radiotherapy for TYA cancer where there is a policy supporting the routine commissioning of conventional photon radiotherapy.

In creating this policy NHS England has reviewed these clinical conditions and the options for treatment. It has considered the place of this treatment in current clinical practice, whether scientific research has shown the treatment to be of benefit to patients, (including how any benefit is balanced against possible risks) and whether its use represents the best use of NHS resources.

This policy document outlines the arrangements for funding of this treatment for the population in England.

Equality statement

NHS England has a duty to have regard to the need to reduce health inequalities in access to health services and health outcomes achieved as enshrined in the Health and Social Care Act 2012. NHS England is committed to fulfilling this duty as to equality of access and to avoiding unlawful discrimination on the grounds of age, gender, disability (including learning disability), gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, gender or sexual orientation. In carrying out its functions, NHS England will have due regard to the different needs of protected equality groups, in line with the Equality Act 2010. This document is compliant with the NHS Constitution and the Human Rights Act 1998.

This applies to all activities for which NHS England is responsible, including policy development, review and implementation.

Plain Language Summary

Teenage and Young Adult (TYA) Cancer is relatively rare (less than 1% of all cancers) with a characteristic pattern of tumour types and incidence. Overall survival is high with greater than 80% of patients surviving 5 years thanks to modern treatments. Radiotherapy is an essential component of modern curative TYA cancer treatment. There are also a spectrum of cancers that are more common in the Paediatric age group and occur with less frequency in the TYA definition group but overlap. However with increasing survival the long term complications that result from the treatment can have a major impact on clinical outcomes; physical (growth, hormonal, fertility) emotional, neuropsychological and social well-being. The growing normal tissues in children and TYA groups can be particularly vulnerable to these effects and the long term effects have a greater impact. There is an incidence of second cancers caused by treatment; an average of 4% that varies according to the disease and body site treated. There is strong evidence that all these risks can be reduced by the use of proton beam radiotherapy.

Proton Beam Radiotherapy refers to the use of high-energy proton beams used instead of conventional X-rays to treat the cancer. It is capable of being targeted to match a high dose treatment to the shape and position of the tumour area within the body. However, because of its characteristic properties to stop at a precise depth in tissue with no dose beyond that point, it can allow treatment with significantly reduced volumes of irradiated normal tissues. It is this property that allows treatment to be delivered with reduced risks of late side effects.

Selected paediatric cases have had treatment approved and funded at selected proton centres abroad, by the NHS since 2008 within the National Specialised Commissioning Team Proton Overseas Programme. This policy expands that programme into a wider group of patients where evidence would also support better outcomes. It defines a subset of patients for whom there is no detrimental effect to having treatment delivered abroad and where clinical gain is highest and the evidence base strongest. It is anticipated that this arrangement will continue until 2018 when a proton service is due to be available in England.

Patients who meet the clinical criteria outlined in this policy are eligible for proton beam radiotherapy and should be considered for it by specialised multidisciplinary teams.

2 Introduction

Proton Beam Radiotherapy (PBT) is a specific type of radiotherapy delivery with unique properties that make it suitable for the treatment of a subset of those patients treated by radiotherapy with curative intent. The main factors separating this subset relates to the ability of protons to:

- Reduce dose to critical normal tissues, thereby reducing late side effects; and/or
- Allowing an increase in delivered dose to the tumour target, especially where this is close to dose limiting normal tissues, and thereby increasing local control and cure rates.

It is relatively expensive compared to conventional radiotherapy and also not available in the UK at present. The indication for treatment abroad in any individual patient has to take into account the complex medical pathways of these rare cancers, the social and personal context and the likelihood of any improved clinical outcomes. The NHS must be mindful of value for money and justify high cost treatments based on selecting only patients who are likely to benefit and where a sufficient evidence base is available.

3 Definitions

Teenage and Young Adult (TYA) Cancer: refers to cancer (less than1% of all cancers) occurring in patients aged 16 – 24 years inclusive (up to 25th birthday). There are 1,700 patients in this age group diagnosed each year in England. It encompasses a wide range of individual diagnoses, each of which is treated according to specific clinical protocols and treatments according to stage and body site. TYA cancers are treated within a context of centralised care patterns and supportive structures that match the specific needs of the patient group, both medical and social. For this reason a specific CRG exists and defines a separate pattern of care.

Proton Beam Radiotherapy: is the use of high-energy proton beams used instead of conventional X-rays to treat cancer. It is capable of being precisely targeted using imaging to match a high dose treatment volume to the shape and position of the tumour area within the body. However, because of its characteristic properties to stop at a precise depth in tissue with, no dose beyond that point, it can deliver treatment with significantly reduced volumes of unnecessarily irradiated normal tissues. It is given in a number of daily treatments over several weeks.

4 Aims and objectives

This policy aims to: Define an appropriate framework for TYA cancer patients to access proton beam radiotherapy. The objectives are to:

- Ensure appropriate TYA Cancer patients have equitable access to Proton Beam Radiotherapy and so improved clinical outcomes, especially in terms of late side effects of treatment; and
- In some cases it may also allow opportunities for improved primary cure rates and reduced treatment related second malignancy.

5 Epidemiology and needs assessment

Most of the cancers affecting children and many TYA age patients differ from those affecting adults. They occur in different parts of the body; appear differently under the microscope, have a different incidence rate and respond differently to treatment. Treatment is frequently complex and intensive but cure rates among children are much higher than for most adult cancers, and overall more than 80% of children are completely cured. A significant proportion of these will experience long-term side effects from their treatment. Children are diagnosed with a wide range of cancers in the UK, around 41% are leukaemia and lymphoma, 25% brain tumours, with the remaining conditions comprising a wide range of solid tumours.

In Great Britain, the world age-standardised incidence rate has increased by more than two fifths (43%) since the late 1960s, from 107 cases per million children in 1966-1970 to 152 cases per million in 2001-2005. Between 1966 and 2000 there has been a statistically significant average annual increase of almost 1% per year, although this varies between 0.5% and 2.5% per year by tumour type. The literature suggests a plateau had been reached in childhood cancer incidence rates from the mid-1990s onwards. Whilst some of the worldwide increases are likely to be due to real changes in risk, improvements in the efficiency of systems for the diagnosis and registration of childhood cancers since the 1960s and 1970s will also have played a part.

Cancer in children is rare, about one in 600 children develops a cancer by age 15 years. It is a collective term for a wide range of individually very rare different diagnoses and cancers. There are approximately 1,400 new cases of cancer among children 0-15 years in the UK each year; an annual incidence rate of approximately 1:7700. The incidence of cancer in adolescents is less certain due to data collection problems, but rates calculated by Birch (2003) and endorsed by the Children's Cancer and Leukaemia Group suggest about 1:7000 per year among adolescents 15-19 years. Across the 0-19 age range, the highest incidence of cancer is among children 0-4 years, reducing among children 5- 14, and rising again among teenagers over 15 years. The incidence of childhood cancer in each region is similar to across the UK.

In children, the most common malignancy is leukaemia, followed by tumours of the central nervous system and then a variety of embryonal tumours. As the age of the patient increases, bone sarcoma and epithelial tumours, which are more commonly seen in adults, are found. In addition, patients across this age range will be at different stages of physical and emotional development and the care setting needs to be responsive to the needs/ age of patients.

Cancer-like disease: There are some very rare cancer-like diseases that are treated under paediatric cancer services. These include:

- Craniopharyngioma: A craniopharyngioma is a benign tumour that develops near the pituitary gland at the base of the brain.

- Juvenile Angiofibroma: Whilst the primary treatment is surgical, radiotherapy is used for incomplete resection and in this age group the same principles apply to reduce avoidable dose to normal tissues as in other indications in the policy.

The list contained within the criteria below necessarily contains a subset of the wide range of rare paediatric cancers extending onto the TYA age group. In 2013 a total of 99 cases were accepted for treatment with proton radiotherapy. There is still significant room for growth and ensuring equity of access with a likely number of up to 150 cases being currently practical to send abroad for treatment without any compromise to other aspects of care in often complex long and multi-modality treatment programmes.

The population of the UK has grown faster than most other European countries in the last few years and stands at 63.7M in 2013 and projected to be 66.3M in 2018. Of particular importance for proton radiotherapy is the current and sustained rise in the birth rate with the UK being second only to France in Europe. This means the relative proportion of the population with paediatric cancer extending into the TYA age group, and thus potentially requiring radiotherapy will rise from past models.

6 Evidence base

Because of the large number of possible indications for radiotherapy and PBT, the degree of variation in clinically important patient and disease parameters, and the limited experience in commoner cancers, it is extremely difficult to evaluate the clinical effectiveness of PBT for every potential clinical condition.

The National Radiotherapy Advisory Group recommendations in 2007 (incorporated into the Cancer Reform Strategy are based on clinical consensus and well referenced, although the level of the evidence is generally poor, being based largely on case series. Other more recent National PBT Programmes and

National Frameworks have consistent conclusions on the clinical benefit for PBT in the selected cancers and clinical situations contained within the PBT policies and for treatment abroad within the Overseas Programme e.g., American Society for Therapeutic Radiology and Oncology (ASTRO) and Dutch, Danish and Swedish National Policies.

There is good clinical evidence for the ability to safely deliver dose escalated radiotherapy with PBT in specific clinical situations to achieve high local control rates and in other areas to avoid unnecessary radiotherapy dose to normal tissues and so reduce the risk of important side effects and risks of radiotherapy induced second malignancy. These latter considerations are particularly important in radiotherapy delivered to paediatric and young persons with cancer, as the cure rates are high.

There is evidence of particular sensitivity to certain side effects in younger patients and that they have a huge personal and financial impact in later life.

There is relatively little published evidence as to the cost-effectiveness of PBT in all different cancer types. NHS England is including a detailed program of evidence review and policy development for PBT within its work programme for both the Overseas Programme and the UK PBT National Service.

7 Rationale behind the policy statement

PBT is a highly complex and expensive form of radiotherapy. The evidence base for many cancers is not clear-cut so a formal process for approval and funding is required to ensure appropriate patients with an ability to gain are selected and costs justified. Because treatment is delivered overseas other factors may need to be taken into account so that overall outcomes can be balanced and cure rates not compromised.

Patients have been receiving PBT abroad within the previous highly specialised commissioning structure since 2008. This policy brings that guidance within the current NHS framework and updates the clinical indications to reflect new evidence and processes.

Paediatric cancer describes a grouping of a large number of different rare cancers for which a single policy is appropriate and where PBT can have common principles applied to justify its use to achieve improved clinical outcomes. Cancers in the TYA age group have a particular incidence but there is an overlap with certain cancers that particularly occur in the paediatric age group. This linked PBT policy for TYA is to allow for this as well as a deliver a policy framework for a future UK based service in 2018 onwards. It overlaps with a highly selected group of rare adult cancers for which there is a sufficient evidence of clinical benefit to commission routinely.

8 Criteria for Commissioning

8.1 Adult (16 or over) Clinical Indications

This policy has been agreed on the basis of NHS England's understanding of the likely price of care associated with enacting the policy for all patients for whom NHS England has funding responsibility, as at the time of the policy's adoption. Should these prices materially change, and in particular should they increase, NHS England may need to review whether the policy remains affordable and may need to make revisions to the published policy.

8.2 General Criteria

A clear indication for radiotherapy, defined as curable, with cancer survival expectation of at least 40% 5 year survival and no comorbidities likely to limit life expectancy to <5 years plus WHO Performance Status 0-1.

There should be NO evidence of distant metastasis with the exception of: Rhabdomyosarcoma and Ewing's Tumours where limited and only lung disease that has a good partial response to the initial radiological reassessment after chemotherapy will be considered for referral and treatment.

8.3 Specific Diagnostic Criteria

- ‘Adult type’ Bone and Soft Tissue Sarcomas (excluding extremities)
- Rhabdomyosarcoma (excluding extremities)
- Ependymoma
- Ewing’s Sarcoma (excluding extremities)
- Retinoblastoma
- Pelvic Sarcoma
- Optic Pathway and other selected Low Grade Glioma
- Craniopharyngioma
- Pineal Parenchymal Tumours (not Pineoblastoma)
- Pelvic Sarcoma
- Optic Pathway and other selected Low Grade Glioma
- Craniopharyngioma
- Pineal Parenchymal Tumours (not Pineoblastoma)
- Non-metastatic intracranial non-germinomatous germ cell tumours
- Pituitary Adenoma
- Juvenile Angiofibroma
- Meningioma (Excluding Grade 3)
- Nasopharyngeal Carcinoma
- Esthesioneuroblastoma
- Salivary Gland Tumours
- High Naso-ethmoid, frontal and sphenoid tumours with Base of Skull involvement
- Adenoid Cystic Carcinoma with perineural invasion

9 Patient pathway

Patients with paediatric and TYA cancers are all considered by specialist MDTs. Treatment may consist of a variable combination of surgery, chemotherapy and radiotherapy in complex pathways, and in many cases within the context of clinical studies or trials.

It is essential that any surgery should have been carried out within expert specialised units to ensure adequate imaging, multidisciplinary care and quality of resection to allow best outcomes of combined modality care required for many of these tumours.

Where radiotherapy is considered and patients are eligible according to these criteria consideration should be made by the MDT for referral for protons and this offered to parents and patients. There may be complex and good medical or social reasons why PBT is not considered to be possible or the best treatment for individual patients. Reasons for patients not being referred should be documented.

Patients will be referred to the NHS England National Proton Clinical Reference Panel for case review and a recommendation on approval for funding to NHS England commissioners. The panel reviews all relevant clinical details and imaging with a target response time for a decision of within 10 working days of receiving a complete application.

On approval, a patient can be referred to the designated proton treatment centre abroad. Clinical details and a formal clinician to clinician referral is then made by the referring clinical oncologist to the proton treatment centre following direct consultation with parents and patient about the aims and objectives of treatment. Imaging may be sent by the Proton Administration team directly to the treatment centre abroad by secure image exchange portal.

If accepted for treatment the practical travel and accommodation arrangements should be made by the referring centre team in conjunction with the proton treatment centre. Travel and accommodation costs will be paid by NHS England in accordance with the published policy (B01/P(HSS)a 2013).

The patient will travel to the proton treatment centre abroad for the duration of assessment, planning and proton treatment. The proton and associated treatment costs will be met by NHS England.

On completion of treatment follow up will be by the referring treatment centre. Clinical Outcomes data is collected on all patients and referring clinicians and teams expected to provide relevant clinical information.

This pathway is a continuance of that of the past National Specialised Commissioning Team (NSCT) agreed pathway.

10 Governance process

The referral process specifies detailed information required from referring clinicians and teams to allow clinical decisions on treatment and care to be made abroad.

As there are currently no high-energy PBT facilities in the UK, NHS England currently commissions proton beam therapy services from three providers, two in the USA and one in Switzerland.

Full treatment details and summaries are communicated directly to referring clinical teams.

PBT aligns with the general principles, concepts and governance linked to the Radiotherapy Clinical Reference Group as described in the general radiotherapy service specification for services within England.

11 Mechanism for funding

PBT, as a highly complex service with treatment delivered overseas is funded through NHS England Specialised services directly. Treatment costs are funded directly through NHS England to treatment centres abroad. Travel and accommodation costs may be met through patients referring centres and hospitals or directly.

Individual funding requests outside of this policy require specialised knowledge and the Proton Overseas Programme National Clinical Reference Panel will be used to support and inform commissioning decisions.

12 Audit requirements

The Proton Administrative team will keep data on activity and treatment and high-level clinical outcomes. It is expected that follow up information will be returned from referring centres. A more detailed late effects scheme is proposed linking into proposals for a UK based service.

13 Documents which have informed this policy

Cancer Reform Strategy (Department of Health, 2007)

http://webarchive.nationalarchives.gov.uk/+/www.dh.gov.uk/en/Healthcare/Cancer/DH_091120

Improving Outcomes: A strategy for Cancer (Department of Health, 2011)

https://www.gov.uk/government/publications/the-national-cancer-strategy

14 Links to other policies

All other policies, clinical guidelines and patient information is available at:

http://www.england.nhs.uk/ourwork/commissioning/spec-services/npc-crg/group-b/b01/

This policy links to other policies within the Proton Overseas Programme. Most specifically it links directly to the Proton Beam Radiotherapy (High Energy) for Paediatric and Adult Cancer Treatment – NHS Overseas Programme.

The transport and accommodation Policy for PBT is available as above. Low energy PBT is available for the treatment of rare ophthalmic cancers in England within the ocular malignancy service specification.

http://www.england.nhs.uk/wp-content/uploads/2013/06/d12-ocular-oncology-ad.pdf

This policy follows the principles set out in the ethical framework that govern the commissioning of NHS healthcare and those policies dealing with the approach to experimental treatments and processes for the management of individual funding requests (IFR).

15 Date of review

This policy will be reviewed in April 2017 unless information is received which indicates that the proposed review date should be brought forward or delayed.